DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species 3 (Figs. 12-17) is filed on 05/18/10. During the Interview on 05/25/10, Applicant re-elected Species 2 (Figs. 6-9).

Applicant's election with traverse of Species 2 (Figs. 6-9) in the reply filed on 05/18/10 is acknowledged. The traversal is on the ground(s) that Examiner has failed to establish that Species 1-6 are so patentably distinct to warrant separate examination, and Examiner has failed to demonstrate that there is an undue burden. This is not found persuasive because the species are distinct. These species are not obvious variants of each other. For example: Species 1 (Figs. 1-5) does not need the spring in the device; while the other Species 2 (Figs. 6-9); Species 4-5 (Figs. 20-25) include the spring. Species 1-2 does not show that the pivoting member is swung about 180 degrees while the other Species includes this claimed structure.

The requirement is still deemed proper and is therefore made FINAL.

As noted, claims 2, 18 drawn in Figs. 13, 26A-D; claim 6 drawn in Figs. 13 or 17; claim 7 drawn in Fig. 17; claim 8 drawn in Fig. 16; claims 9-14 drawn in Fig. 20; claims 15, 21 drawn in Fig. 12; claim 19 drawn in Figs. 26A-D (page 15-16 of Specification);

Therefore, claims 2, 5-15, 18-19, 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species 1, 3-6, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/18/10 and oral interview 05/25/10.

Claims 1, 3-5, 16-17, 20, 22-24 are present for examination.

Drawings

The drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

New corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in this application **because the drawings are too dark, and difficult to see**. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "the release means for disengaging the first locking means comprises two positions placed on opposite sides of the housing" is vague. Does Applicant mean that: a) the release means comprises two positions placed on opposite sides of the housing; or b) the first locking means comprises two positions placed on opposite sides of the housing?

For examining purpose, Examiner interprets the limitation of claim 17 such as: the first locking means comprises two positions placed on opposite sides of the housing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 16-17, 20, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsals et al. (US 5,858,001).

As noted that the recitation "…for the subcutaneous introduction of a cannula of an infusion part into the skin of a patient" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Regarding claims 1, 3-4, 16, 22-24, Tsals discloses an injector device (in Figs. 1-3, 16-20) comprising:

a housing 10, 110 including a back 11 (Fig. 1) or (a proximal portion away from the needle portion), and longitudinally extending guiding means 12, 112;

a slidable member 16 (Figs. 1-3) or 123 and 111 (Figs. 16-20) longitudinally slidable within the housing;

an insertion needle 21, 129;

a spring 23, 128 located between the back of the housing and the longitudinally slidable member;

first locking means 26, 116 for maintaining the spring in a compressed state; and

release means (pressure is exerted on top surface of device, col. 9, lines 40-50; col. 13, lines 15-20) for disengaging the locking means; and

a pivoting member/a hinge fastened to the slidable member, the pivoting member being pivotable from a position in which the pivoting member allows for insertion of the needle into a position in which it the pivoting member embraces the needle, see Fig. 2 or Fig.17.

Regarding claim 5, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. the pivoting member can embrace the needle when the slidable member is in a forward position and the spring is in a released state, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). In this case, the device of Tsals is capable of performing the requirement of claim 5 as shown in Fig. 2 or Fig. 17.

Regarding claim 17, as best as understood, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. the release means for disengaging the first locking means comprise two positions placed on opposite sides of the housing, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). In this case, the device of Tsals is capable of performing the requirement of claim 17. For example, the first position of locking means 26 or 116 shown in Figs. 1 and 16; the second position of locking means 26 or 116 shown in Figs. 2 and 17.

Regarding claim 20, the term “pivoting member can embrace the needle” is considered as functional limitation. In this case, the pivoting of Tsal is capable of performing the function such as the pivoting member can embrace the needle and using the force applies on the surface of device, the slidable member is still in a retracted position and the spring is in compressed state.

Claims 1, 3-5, 16-17, 20, 22-24 are alternatively rejected under 35 U.S.C. 102(b) as being anticipated by Marano et al. (US 5,851,097) or Safabash et al. (US 2006/0069351).

Marano or Safabash discloses an injector device comprising:

a housing 34 including a back 82 (Fig. 5) or (a proximal portion away from the needle portion), and longitudinally extending guiding means 28;

a slidable member 94 longitudinally slidable within the housing;

an insertion needle 12;

a spring 36 located between the back of the housing 34 and the longitudinally slidable member 94;

first locking means (element 58 locked by element 68, Figs. 9 or 14) or 78 for maintaining the spring in a compressed state; and

release means 38, 78 for disengaging the locking means; and

a pivoting member 98 fastened to the slidable member 94, the pivoting member being pivotable from a position in which the pivoting member allows for insertion of the needle into a position in which it the pivoting member embraces the needle, see Figs. 7 and 15.

The device of Safabash is similarly to the device of Marano and discussed above. The device of Safabash in Figs. 41-46 also discloses all claimed subject matter. The device in Figs. 41-46 of Safabash comprising: a housing 600; a slidable member 603 (Fig. 43); an insertion needle 702; a spring; a first locking means showed in Fig. 41; a release means (a button); a pivot member having pivot member fastened to the slidable member, the pivoting member being pivotable from a position in which the pivoting member allows for insertion of the needle (para [0108]).

A Suggestion for Allowable Subject Matter

Claim 1 would be allowable if rewritten in independent form including all of the limitations as following:

1. (Currently Amended) An injector device for the subcutaneous introduction of the a cannula of an infusion part into the skin of a patient, said device comprising:

a housing including a back and longitudinally extending guiding means;.

a slidable member-longitudinally slidable within the housing;

an insertion needle for insertion of said cannula;

a spring located between the back of the housing and the longitudinally slidable member;

a pivoting member;

a first locking means located on said pivoting member ; said first locking means engaging at the back of the housing for maintaining or locking the spring in a compressed state;

a release means (39) for disengaging the locking means ;

when the release means are disengaged, the spring drives the slidable member to its forward position; wherein said pivoting member swung away and opposite with said backing of the housing when the pivoting member is embracing the needle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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